

Methods: Of 380 patients from Europe registered in the MFM Global Registry after treatment for thoracoabdominal aortic aneurysm (TAAA) or dissection, 38 (10%) patients (30 men; median age 71 years, range 30–91) treated a compassionate basis outside the IFU were analyzed. Thirteen patients had chronic Stanford type B dissection with aneurysmal dilatation >6 cm. There were 6 mycotic and 4 saccular aneurysms in addition to 15 primary TAAAs. The mean aneurysm diameter was 7.1 cm. Ten patients presented with rupture, and 23 patients had previous open or thoracic endovascular aortic repair (TEVAR).

Results: Although no death, paraplegia, stroke, or renovisceral compromise was documented during the initial hospital stay, technical success was zero. There were 31 cases (81.6%) in which there was failure to land the device in normal aorta. Other violations of the IFU included 12 with inadequate stent overlap and 11 cases involving a small MFM being deployed inside a larger one. Overall survival, freedom from aneurysm-related death, and rupture-free survival estimates were 17.5%, 25.0%, 31.5%, respectively, at 18 months. There were 8 visceral branch complications; in all, 14 secondary endovascular interventions were required in 11 patients for endoleak or stent foreshortening. No false lumen was completely thrombosed in the dissecting aneurysms. All aneurysms showed a mean sac growth rate of 0.12 ± 0.16 cm/month. Factors having a significance influence on risk of aneurysm-related death included aneurysm diameter ($p=0.025$), previous TEVAR ($p=0.03$), and inadequate overlap between devices ($p<0.002$).

Conclusions: There are clinical scenarios in which the MFM does not perform well. MFM is not a solution for patients living on borrowed time and should not be used indiscriminately in patients in whom other modalities of aortic repair are not feasible. It use must adhere to the IFU, and robust clinical data are required before constructing a randomized controlled trial.

TCT-566

Impact of Type-II Endoleak on Aneurysm Sac Growth and Predictors of Type-II Endoleak after Endovascular Aneurysm Repair

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Background: Type-II endoleak(T-II) after endovascular abdominal aneurysm repair(EVAR) is an unresolved phenomenon. We aimed to investigate the impact of T-II on aneurysm sac growth and reveal preoperative T-II predictors.

Methods: We enrolled 162 consecutive patients (Zenith:61, EXCLUDER:57, ENDURANT:44) who underwent successful EVAR without Type-I or Type-III endoleak and had at least 1-year follow-up. Computed tomography(CT) before and after EVAR(1 week, 6 months, and 1 year) were reviewed to estimate T-II and measure sac diameter. Three-dimensional volume analyses were performed during CT for measuring sac volume. Vessel number and diameter of the patent lumbar artery(LA) and inferior mesenteric artery(IMA) were evaluated. Variable anatomical parameters and patient characteristics were investigated as possible T-II predictors.

Results: T-II was 35.8%, 15.4%, and 12.3% at 1 week, 6 months, and 1 year after EVAR, respectively. The mean preoperative maximum sac diameter and volume were 50.1 ± 8.2 mm and 153.8 ± 75.5 ml, respectively, without differences between T-II cases(T-II-group) and absence of T-II cases(non-T-II-groups). Significant differences in the reduction of sac diameter(T-II-group: -0.11 ± 3.4 mm vs non-T-II-group: -7.3 ± 6.0 mm $p<0.0001$) and volume(T-II-group: -0.07 ± 14.6 ml vs non-T-II-group: -24.2 ± 30.7 ml $p=0.0007$) was observed between two groups at the 1 year after EVAR. Sac growth was observed in 47.6% cases in the T-II-group. EXCLUDER use, patent LA, patent IMA, and IMA diameter were significantly associated to T-II at 1 week after EVAR in univariate analysis. Dual antiplatelet therapy(DAPT), EXCLUDER use, number of LA and patent IMA were significantly associated to T-II at 1 year after EVAR. Multivariate analysis revealed that DAPT and EXCLUDER use were independent predictors of T-II at 1 year after EVAR. Patent IMA was the only significant correlative factor of sac growth in patients with persistent T-II.

Conclusions: Persistent T-II after EVAR was observed in 12% cases. DAPT and EXCLUDER use were independent predictors of persistent T-II. Sac growth was observed in half of the patients with persistent T-II. Because T-II with patent IMA was significantly associated with sac growth, careful observation or additional

TCT-567

Intravascular Ultrasound Guidance for Percutaneous Treatment of Aortic Coarctation

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Background: Percutaneous treatment of aortic coarctation (AC) is usually guided with intravascular contrast injections and hemodynamic parameters. Intravascular ultrasound (IVUS) guidance might be useful to choose adequate balloons and stents sizes and to optimize the final result after angioplasty, but there are few reports in the literature.

Methods: Eleven patients (91% male), mean age 24 ± 18 years (range 7–63), with a diagnosis of native AC (36%) or recoarctation (64%) confirmed with non-invasive imaging techniques (echocardiography and magnetic resonance or computerized tomography), were included. Simultaneous radial and femoral access was used in all cases.

After standard aortography in 2 projections (lateral and anteroposterior), the anatomy of the aorta was studied with IVUS (Ultra ICE 9F 9MHz®, Boston Scientific) from the arch down to the diaphragm, and again after the angioplasty was performed.

Results: The procedure was successful in all cases. Mean gradient changed from 33 ± 9 mmHg (baseline) to 4 ± 5 mmHg (final). Minimal lumen diameter of the AC with angiography was 8.1 ± 2.2 mm and with IVUS 9.4 ± 1.9 mm ($p<0.05$). Stents were implanted in 10 patients (91%), in seven cases covered stents were used and bare metal stents in the rest. One patient was treated only with high pressure inflation of a non-compliant balloon inside a previously implanted stent. Mean diameter of the balloons where the stent was mounted was 15.6 ± 2.9 mm (12–22), mean length of the stent was 35.5 ± 5.3 mm (28–45), and mean diameter of postdilatation balloons was 17 ± 4.2 mm (12–25). Intrastent postdilatation was performed in 73% of cases, mainly due to significant stent infraexpansion detected with IVUS. All patients were discharged in 24–48 hours without significant complications. The use of IVUS changed the initial strategy, based only in angiography, in 73% of cases (balloon size, stent length or need for postdilatation).

Conclusions: IVUS guidance during percutaneous treatment of AC modifies in a high percentage of cases the treatment strategy based only in angiography. There are significant anatomic differences between angiographic and IVUS measures.

TCT-568

THE MULTILAYER FLOW MODULATOR STENT FOR THE TREATMENT OF THORACIC ABDOMINAL AND ABDOMINAL AORTIC ANEURYSMS. MOROCCAN EXPERIENCE

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Background: Thoracic Abdominal Aortic Aneurysms (TAAA) and Abdominal Aortic Aneurysms (AAA) are traditionally treated surgically, but more and more by interventional procedures (endografts, fenestrated, branched grafts, chimney techniques). We used a new concept of stent, the Multilayer Stent Flow Modulator (M.F.M) to treat these aneurysms (A) and try to avoid some major complications.

Methods: This selfexpandable M.F.M is a 3 D braided tube made of several interconnected layers without any covering. We will explain and demonstrate the key principles of the stent leading to thrombosis, shrinkage of the A, eliminating the risk of rupture. Moreover, this M.F.M preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels...)

Results: 10 TAAA, 8 AAA (7 extended to both iliac arteries) treated with MFM in very high risk patients. 53 MFM implanted (1 to 5 per pt). o Technical success: 100% o At 30 days: no neurological complication, branch patency 100%, no death o During the follow up we had 3 deaths not device related. CT scan control performed at 1, 3, 6, 12, 18 months with calculation of A. Diameters and Volumes. o All collateral branches remain patent and we observed a progressive thrombosis and shrinkage of the aneurysmal sac depending on the size of the collaterals. Some patients developed a thrombus after 1 month, some after 6 months and some even after 18 months. o A significant mean diameter reduction was observed between baseline and 6 months: 17,25 mm reduction for the transversal diameter, 13,83 mm for the antero posterior diameter in the TAAA group. o Overtime the ratio thrombus volume / Total Volume is increasing and the ratio Residual Flow Volume / Total Volume is decreasing. The problems of thrombosis, shrinkage and volume reduction of the aneurysmal sac will be discussed. The complications rates with M.F.M appear lower in comparison with current endovascular techniques, and with surgery.

Conclusions: The M.F.M represents an alternative to current devices to treat TAAA and AAA. It is a safe procedure with a low complication rate. The first results are promising. A larger study is ongoing.

TCT-569

Aortic Dissection and Mortality During Pregnancy in the United States: A 10-Year Analysis

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Background: Aortic dissection during pregnancy is a morbid condition for both the mother and her fetus. There is scant data on the incidence, risk factors, and outcomes of aortic dissection during pregnancy.

Methods: The Nationwide Inpatient Sample (NIS) Database was queried for cases of pregnancy and aortic dissection from 1998–2008. The primary analysis identified specific medical co-morbidities increasing the risk of aortic dissection during pregnancy.

Results: We identified 10,550,421 pregnant women and 41,088 aortic dissections in the NIS Database from 1998–2008. From these cases, we identified 44 cases of aortic dissection in pregnancy. The rate of aortic dissection in pregnancy was .0004%, and represented only 0.1% of all cases of aortic dissection. Mean age of aortic dissection was younger (31-years-old vs. 69-years-old). The incidence of Marfan's syndrome was higher (15.9% vs. 1.8%, $p<0.00001$) and the incidence of hypertension was lower (18.2% vs. 68.3%, $p<0.00001$). 14 out of the 44 pregnant patients with aortic dissection underwent operative repair of the aorta. Patient death was lower in cases of aortic dissection during pregnancy compared to the general population (6.8% vs. 15.4%, $p<0.03$).

Conclusions: Aortic dissection during pregnancy is an extremely rare event with a significantly higher incidence of Marfan's Syndrome but lower incidence of mortality.